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21 January 2000

Centeon
1020 First Avenue
King of Prussia, PA
19406-1310

610 878-4000
610 878-4009 Fax

Food and Drug Administration
Center for Biologics Evaluation and Research
Attn: Dockets Management Branch (HFA-305, Room 1061)
5630 Fishers Lane
Rockville, MD 20852

Re: Draft Guidance "Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma" (Docket No. 99D-4577)

This draft guidance was issued for comment based upon requests from manufacturers for guidance in the development of nucleic acid testing of pooled plasma for infectious agents. We commend the agency on its effort to seek industry comment on implementation of nucleic acid testing intended for use in blood screening and/or manufacturing of blood products.

However, due to the complexity of submission alternatives for nucleic acid testing we are requesting an extension of the comment period. We feel this additional time will be necessary to prepare constructive comments in collaboration with our international colleagues. We also feel that nucleic acid testing may be more sensitive than other methods currently available for early detection of virus during the pre-seroconversion phase of infection and may, therefore, have an added value in blood safety. For these reasons we urge the FDA to consider our request for extension.

Aventis Behring L.L.C. (formerly Centeon L.L.C.) appreciates the opportunity to comment on this draft guidance. If you have any questions regarding this letter please feel free to contact me at (610) 878-4196.

Sincerely,

AVENTIS BEHRING L.L.C.

Jan Fuller Farrar, RAC
Senior Director
Regulatory Affairs

99D-4577

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